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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,907	04/20/2004	Michael T. Barrett	10031034-1	5662

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
03/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,907	BARRETT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 30 November 2007 in which claims 1, 3, 15 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 4 September 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-16 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiegler et al (Genes, Chromosomes & Cancer, April 2003, 36: 361-374).

Regarding Claim 1, Fiegler et al disclose a method of assessing surface-bound polynucleotide, the method comprising, mixing pre-determined amounts of individual mammalian chromosomes to produced non-cellular composition (flow-sorted chromosome 1 composition, page 364, last paragraph), contacting a labeled nucleotides made from the chromosome composition (DOP-PCR amplified genomic DNA) with an array of surface-bound probes and evaluating binding of the probes to the labeled nucleotides relative to a second population from a reference composition (male vs female + chromosome 1 DNA, paragraph spanning pages 364-365).

Regarding Claim 2, Fiegler et al disclose the method wherein the first and second populations are differentially labeled (Cy3 vs Cy5, paragraph spanning pages 364-365).

Regarding Claim 3, Fiegler et al disclose the method wherein the surface-bound probes bind a sequence present in a chromosome in the non-cellular composition and the reference (i.e. chromosome 1, page 368-369).

Regarding Claim 4, Fiegler et al disclose the method wherein chromosome 1 is present in a predetermined ratio in non-cellular and reference compositions (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 5, Fiegler et al disclose the method wherein the ratio is an integer, 1, 2 or 4 extra copies (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 6, Fiegler et al disclose the method wherein the non-cellular chromosome composition contains chromosome 1 (page 364, left column last paragraph, first 3 lines).

Regarding Claim 7, Fiegler et al disclose the method wherein chromosome 1 is present in present at a level not naturally occurring in a mammalian cell (i.e. 1, 2 or 4 additional copies, paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 8, Fiegler et al disclose the method wherein the non-cellular composition contains all chromosomes from the female and one or more chromosome 1, not naturally occurring in a mammalian cell (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 9, Fiegler et al disclose the method wherein the surface-bound probe is an oligonucleotide (page 363).

Regarding Claim 10, Fiegler et al disclose the method further comprising isolating a chromosome (i.e. chromosome 1) from a mammalian cell to provide the non-cellular composition (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 11, Fiegler et disclose a method of assaying a candidate surface-bound probe for suitability for use in array-based CGH by assessing binding of the probe on an array according to Claim 1 (page 362, paragraph spanning left and right columns).

Regarding Claim 12, Fiegler et al disclose the method wherein surface-bound probe binds to the first and second population at a level corresponding to the level of the chromosome in the compositions (page 369, left column).

Regarding Claim 13, Fiegler et al disclose the method wherein the chromosome is predetermined as chromosome 1 (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 14, Fiegler et al disclose the method wherein the array comprises a plurality of different surface-bound probes (page 364-365).

Regarding Claim 15, Fiegler et al disclose the method comprises assessing binding of surface-bound probes to chromosome composition probes made from a chromosome composition comprising all chromosomes of an animal cell (i.e. male and female genomic DNA (paragraph spanning pages 364-365 and pages 368-369).

Regarding Claim 16, Fiegler et al disclose the method further comprising identifying probes suitable for use in array-based CGH (page 362, paragraph spanning left and right columns).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchard (WO 01/06013, published 25 January 2001) in view of Fiegler et al (Genes, Chromosomes & Cancer, April 2003, 36: 361-374).

Regarding Claim 1, Buchard discloses a method of assessing a surface-bound probe (Abstract), the method comprising contacting first and second labeled populations of nucleic acids with the surface bound probes and evaluating the binding of the probes to the labeled populations (Claims 1-19, Fig. 1). Buchard teaches the method wherein labeled population is made from non-cellular chromosome composition (i.e. genomic DNA, page 14, lines 15-28) synthesized by mixing predetermined amounts of individual chromosomes (i.e. the target nucleic acids are synthesized enzymatically from samples present in known amount or abundance, pages 27-35). Buchard does not teach mixing a predetermined amount of individual mammalian chromosome to produce a non-cellular composition.

However, Fiegler et al teach the similar method wherein a composition comprising flow-sorted chromosome 1 is provided, labeled and used is specified ratios to evaluate binding of surface-bound probes. Fiegler et al teach the chromosome composition is an efficient tool for identifying non-overlapping probes to thereby improve accuracy of CGH array data (page 373, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the chromosome composition of Fiegler to the probe analysis of Buchard. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of efficiently identifying non-overlapping probes to thereby improve accuracy of CGH array data as taught by Fiegler (page 373, last paragraph).

Regarding Claim 2, Buchard discloses the method wherein the labeled populations are distinguishably labeled (page 35, lines 34-36).

Regarding Claim 3, Buchard teaches the method wherein the test and reference population bind to the same surface-bound probe (pages 36-37).

Regarding Claim 4-5, Buchard teaches the method wherein the chromosomes of the composition are present in a pre-determined ratio of whole numbers (page 14, lines 15-28).

Regarding Claim 6, Buchard teaches the method wherein the chromosomes are human (page 15, lines 21-24).

Regarding Claims 7-8, Buchard discloses the method wherein at least one chromosome of the composition is at a level not naturally occurring in nature and the composition comprise all chromosomes (e.g. deletion strain from a bacterial cell, page 15, lines 16-20).

Regarding Claim 9, Buchard discloses the method wherein the surface-bound probe is an oligonucleotide (Abstract).

Regarding Claim 11-16, Buchard discloses the method of Claim 1 wherein candidate probe are evaluated for use in array-base hybridization (Abstract) wherein the array comprises a plurality of different probes (Abstract) and further comprising identifying probes suitable for use in array-based comparative hybridization (Abstract, page 2293 and page 2302, right column). Buchard does not teach mixing a predetermined amount of individual mammalian chromosome to produce a non-cellular composition.

However, Fiegler et al teach the similar method wherein a composition comprising flow-sorted chromosome 1 is provided, labeled and used is specified ratios to evaluate binding of surface-bound probes. Fiegler et al teach the chromosome composition is an efficient tool for identifying non-overlapping probes to thereby improve accuracy of CGH array data (page 373, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the chromosome composition of Fiegler to the probe analysis of Buchard. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of efficiently identifying non-overlapping probes to thereby improve accuracy of CGH array data as taught by Fiegler (page 373, last paragraph).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

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